K123492
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# 510(k) Summary of Safety and Effectiveness

DEC 1 3 2012

**Submitted By:**

Philips Medical Systems Nederland BV
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**Registration No:** 3003768277

**Date:** November 9, 2012

**Contact Person:**

Lisa Simpson
Regulatory Engineer / Philips Healthcare
Tel: (352) 336-0010 ext. 164
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**Proprietary Names:** Philips Ingenia 1.5T & Ingenia 3.0T devices:

| | |
|---|---|
| dS Anterior 1.5T | dS Anterior 3.0T |
| dS Base 1.5T | dS Base 3.0T |
| dS Head-Neck 1.5T | dS Head-Neck 3.0T |
| dS Head 1.5T | dS Head 3.0T |
| Flex S 1.5T | Flex S 3.0T |
| Flex M 1.5T | Flex M 3.0T |
| Flex L 1.5T | Flex L 3.0T |

**Common Name:** Coil, Magnetic Resonance, Specialty

**Classification Name and Reference:** 21 CFR 892.1000
A magnetic resonance diagnostic device, for general diagnostic use to present images which reflect the spatial distribution and/or magnetic resonance spectra which reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance, class II.

**Device Product Code and Panel Code:** MOS / Radiology / 90

**Device Description:**
The 510(k) subject devices are magnetic resonance coil is designed and intended for use with Philips 1.5T & 3.0T Magnetic Resonance Imaging (MRI) systems. The MR Coil devices work in unison with the Body Coil of the MRI system, which will transmit the radio frequency (RF) signals, so the coil may receive the resultant RF signal from the excited nuclei. The coil is designed as receive only for high resolution diagnostic imaging of internal body structures.

# 510(k) Summary of Safety and Effectiveness

**Indications for Use:**
The Ingenia 1.5T and Ingenia 3.0T are magnetic resonance diagnostic devices that produce cross-sectional images, spectroscopy images and/or spectra in any orientation of the internal structure of the whole body. These images when interpreted by a trained physician, yield information that may assist in diagnosis.

In addition, the Ingenia 1.5T and Ingenia 3.0T devices provide capabilities to perform interventional procedures in the head, body and extremities, which may be facilitated by MR techniques, such as real time imaging. Such procedures must be performed with MR compatible instrumentation as selected and evaluated by the clinical user.

**Technological Characteristics:**
The fundamental scientific technology of a radio frequency (RF) coil is that the coil receives radio frequency signals from the anatomy of interest.

**Substantial Equivalence Information:**
When compared to the predicate MRI Coil devices (K110151, cleared 03/22/11), substantial equivalency of the 510(k) subject devices is based on design similarities and the same indications for use. The scope of this Special 510(k) is supplemental labeling to allow the MRI coil accessory devices to be packaged and labeled at another facility owned by Philips. There are no changes to the electrical or mechanical design of the MRI coil devices and no changes to the indications for use. The new labeling does not supplant any of the labeling for the MRI system as described in K110151.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 13, 2012

Philips Medical Systems-Nederland BV
% Ms. Lisa Simpson
Regulatory Engineer
Philips Medical Systems-Invivo Corporation
3545 W 47th Avenue
GAINESVILLE FL 32608

Re: K123492
Trade/Device Name: Philips Ingenia 1.5T & 3.0T MR Coil Devices: dS Anterior 1.5T, dS Base 1.5T, dS Head-Neck 1.5T, Flex S 1.5T, Flex M 1.5T, Flex L 1.5T, dS Anterior 3.0T, dS Base 3.0T, dS Head-Neck 3.0T, dS Head 3.0T, Flex S 3.0T, Flex M 3.0T, Flex L 3.0T
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: November 9, 2012
Received: November 13, 2012

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

# Indications for Use

**510(k) Number (if known):** k123492

**Device Name:** Philips Ingenia 1.5T & Ingenia 3.0T MR Coil Devices:

| | |
|---|---|
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
(Division Sign Off)
2012.12.13 12:10:30 -05'00'
Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123492